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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>12D0667110       | <b>(X3) Date Survey Completed</b><br><br>12/04/2025 |
| <b>Name of Provider or Supplier</b><br><br>Ken C Arakawa Md, Inc   | <b>Street Address, City, State</b><br><br>1329 Lusitana St Ste 206, Honolulu, HI |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5209</b>              | <p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b><br/>CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:<br/>The surveyor's review of laboratory records, and confirmation by the general supervisor during an interview on 12/04/2025 at 11:00 AM revealed the laboratory failed to follow its written policy and procedure to assess the competency of 1 of 1 general supervisor in 2023 and 2024. The general supervisor stated that an annual competency assessment was not performed since 2023 when testing personnel responsibilities were removed from the role of general supervisor. The laboratory performs an annual volume of 438 general immunology tests, 30,995 routine chemistry and urinalysis tests, and 22,188 hematology tests.</p> |
| <b>D5211</b>              | <p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b><br/>CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:<br/>The surveyor's review of American Proficiency Institute (API) proficiency testing records, and an interview with the general supervisor and 1 of 1 testing personnel on 12/04/2025 at 11:00 AM revealed the laboratory failed to review and evaluate an unacceptable phosphorus result in the second Chemistry Core event of 2025. The findings include: 1. The laboratory reported a phosphorus result of 4.9 for Specimen</p>   |

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|                     | <p>CH-07. The expected result range was 3.9 to 4.8. 2. The laboratory performs an annual volume of 280 phosphorus tests.</p>  |
| <p><b>D6092</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/> CFR(s): 493.1445(e)(4)(iv)</p> <p>(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;</p> <p>This STANDARD is not met as evidenced by:<br/> The surveyor's review of American Proficiency Institute (API) proficiency testing records, and an interview with the general supervisor and 1 of 1 testing personnel on 12/04/2025 at 11:00 AM revealed the laboratory director failed to ensure an approved corrective action plan was followed for an unacceptable phosphorus result in the second Chemistry Core event of 2025. See D tag D5211.</p>  |
| <p><b>D6103</b></p> | <p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b><br/> CFR(s): 493.1445(e)(13)</p> <p>(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by:<br/> The surveyor's review of laboratory records, and confirmation by the general supervisor during an interview on 12/04/2025 at 11:00 AM revealed the laboratory director failed to ensure the competency of the individual in the position of the general supervisor was assessed in 2023 and 2024. See D tag D5209.</p> |